

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

BAUSCH HEALTH COMPANIES INC.;
SALIX PHARMACEUTICALS, INC.;
PROGENICS PHARMACEUTICALS, INC.;
and WYETH LLC,

Plaintiffs,

v.

GLAND PHARMA LIMITED,

Defendant.

Civil Action No. 22-00939 (EP) (LDW)

Document Electronically Filed

STIPULATED CONSENT JUDGMENT

Whereas Plaintiffs Bausch Health Companies Inc. (“Bausch”), Salix Pharmaceuticals, Inc. (“Salix”), Progenics Pharmaceuticals, Inc. (“Progenics”) and Wyeth LLC (“Wyeth”) and Defendant Gland Pharma Limited (“Gland”) have agreed to the terms and conditions representing a negotiated settlement of this action and have set forth those terms and conditions in a Confidential Settlement and License Agreement (the “Settlement Agreement”),

IT IS HEREBY STIPULATED AND AGREED, by and between Plaintiffs and Gland, through their undersigned counsel of record, that:

1. In the event that the claims of Plaintiffs’ U.S. Patent No. 8,552,025 (“the ’025 Patent”), U.S. Patent No. 9,669,096 (“the ’096 Patent”), U.S. Patent No. 10,376,584 (“the ’584 Patent”), U.S. Patent No. 8,247,425 (“the ’425 Patent”), U.S. Patent No. 8,420,663 (“the ’663 Patent”), U.S. Patent No. 8,822,490 (“the ’490 Patent”), U.S. Patent No. 9,180,125 (“the ’125 Patent”), and U.S. Patent No. 9,492,445 (“the ’445 Patent”) asserted against Gland are not held invalid or unenforceable, absent a license or other authorization from Plaintiffs, the ’025 Patent, the ’096 Patent, the ’584 Patent, the ’425 Patent, the ’663 Patent, the ’490 Patent, the ’125 Patent,

and the '445 Patent would be infringed by any unlicensed manufacture, sale, offer for sale, use, or importation in the United States of the generic product that is the subject of Gland's Abbreviated New Drug Application No. 216836 (the "Gland Vial Product," as defined in the Parties' Settlement Agreement).

2. In the event that the claims of Plaintiffs' U.S. Patent No. 8,552,025 ("the '025 Patent"), U.S. Patent No. 9,669,096 ("the '096 Patent"), U.S. Patent No. 10,376,584 ("the '584 Patent"), U.S. Patent No. 8,247,425 ("the '425 Patent"), U.S. Patent No. 8,420,663 ("the '663 Patent"), U.S. Patent No. 8,822,490 ("the '490 Patent"), U.S. Patent No. 9,180,125 ("the '125 Patent"), and U.S. Patent No. 9,492,445 ("the '445 Patent") asserted against Gland are not held invalid or unenforceable, absent a license or other authorization from Plaintiffs, the '025 Patent, the '096 Patent, the '584 Patent, the '425 Patent, the '663 Patent, the '490 Patent, the '125 Patent, and the '445 Patent would be infringed by any unlicensed manufacture, sale, offer for sale, use, or importation in the United States of the generic product that is the subject of Gland's Abbreviated New Drug Application No. 216965 (the "Gland PFS Product," as defined in the Parties' Settlement Agreement).

3. Gland and anyone acting on the behalf of Gland, except as expressly licensed by Plaintiffs, will be enjoined until expiration of the '025 Patent, the '096 Patent, the '584 Patent, the '425 Patent, the '663 Patent, the '490 Patent, the '125 Patent, and the '445 Patent from (i) making, using, offering to sell, selling, or importing until expiration of the '025 Patent, the '096 Patent, the '584 Patent, the '425 Patent, the '663 Patent, the '490 Patent, the '125 Patent, and the '445 Patent the Gland Vial Product in the United States, and (ii) participating in the profits from making, using, offering to sell, selling, or importing the Gland Vial Product in the United States,

and (iii) indemnifying others with respect to any making, using, offering to sell, selling, or importing the Gland Vial Product in the United States.

4. Gland and anyone acting on the behalf of Gland, except as expressly licensed by Plaintiffs, will be enjoined until expiration of the '025 Patent, the '096 Patent, the '584 Patent, the '425 Patent, the '663 Patent, the '490 Patent, the '125 Patent, and the '445 Patent from (i) making, using, offering to sell, selling, or importing until expiration of the '025 Patent, the '096 Patent, the '584 Patent, the '425 Patent, the '663 Patent, the '490 Patent, the '125 Patent, and the '445 Patent the Gland PFS Product in the United States, and (ii) participating in the profits from making, using, offering to sell, selling, or importing the Gland PFS Product in the United States, and (iii) indemnifying others with respect to any making, using, offering to sell, selling, or importing the Gland PFS Product in the United States.

5. Notwithstanding any provision of the foregoing, Gland shall be entitled to contest the infringement, validity and/or enforceability of the '025 Patent, the '096 Patent, the '584 Patent, the '425 Patent, the '663 Patent, the '490 Patent, the '125 Patent, and the '445 Patent in any future litigation over the '025 Patent, the '096 Patent, the '584 Patent, the '425 Patent, the '663 Patent, the '490 Patent, the '125 Patent and/or the '445 Patent pertaining to any product that is not the Gland Vial Product, is not the Gland PFS Product and is not the subject of the Gland ANDAs (as defined in the Parties' Settlement Agreement).

6. Each party will bear its own attorneys' fees and costs.

7. This Court will retain jurisdiction to enforce this Stipulated Consent Judgment and the parties' related agreements resolving this matter.

8. Plaintiffs acknowledge that Gland is entitled to maintain its Paragraph IV certification to the '025 Patent, the '096 Patent, the '584 Patent, the '425 Patent, the '663 Patent,

the '490 Patent, the '125 Patent, and the '445 Patent pursuant to 21 C.F.R. § 314.94(a)(12)(v). Each Party acknowledges and agrees that the 30-month stay with respect to the approval of the Gland ANDAs under 21 U.S.C. § 355(j)(5)(B)(iii) is hereby terminated.

9. The Clerk of Court is directed to enter this Stipulated Consent Judgment.

STIPULATED AND AGREED TO BY:

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SO ORDERED this 25 day of July, 2022



Honorable Claire C. Cecchi, U.S.D.J.